F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (*admitted pro hac vice*)
Aaron P. Maurer (*admitted pro hac vice*)
Rachel Shanahan Rodman (*admitted pro hac vice*)
Adam D. Harber (*admitted pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P.,

Counterdefendants.

CASE NO.: 08-CV-0133 RMW

DEFENDANT SENORX, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

REDACTED VERSION

Date: June 25, 2008
Time: 2:00 p.m.
Courtroom: 6, 4th Floor
Judge: Hon. Ronald M. Whyte

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PRELIMINARY STATEMENT

By asserting that numerous claim terms should be accorded their "plain meaning," Plaintiffs attempt to circumvent this Court's role in construing the claims of the patents-in-suit. Plaintiffs' motive is easy to discern. They seek the freedom to argue claim construction to the jury – for example, that a "plurality" of sources is met by a single source. And that an "inner, closed chamber" is not inner, and not closed. And that spacing that is "constant" means spacing that can change. But the law requires this Court, not the jury, to construe the claims, *see Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-89 (1996) (judges "are the better suited to find the acquired meaning of patent terms"), and Plaintiffs' invitation to leave these disputed claim terms unconstrued so they can present unsupported (and unsupportable) claim construction arguments to the jury should be declined. "When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008); *id.* at 1361 ("A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when . . . reliance on a term's 'ordinary' meaning does not resolve the parties' dispute."). In this case, as in *O2 Micro*, "the 'ordinary' meaning of a term does not resolve the parties' dispute, and claim construction requires the court to determine what claim scope is appropriate in the context of the patents-in-suit." *Id.*

Plaintiffs also suggest that SenoRx's constructions unnecessarily add structures that are not part of the claim. That is wrong. As will be explained below, in each instance, the specification and/or prosecution history require the structure be included as part of the claim. Indeed, it is Plaintiffs who run afoul of the purposes of claim construction by seeking to cover devices they did not conceive of, describe, or claim. Plaintiffs' motive is yet again clear – Plaintiffs want the Court to avoid precisely defining the claims so that they later can argue to the jury that devices clearly outside the claims infringe.

CONSTRUCTION OF THE DISPUTED TERMS[1]

I. "PLURALITY"

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
Plurality of radioactive solid particles placed at predetermined locations ('813 patent, claim 12)	Two or more separate radioactive solid particles placed in the inner spatial volume at the same time at more than one predetermined location.	No construction necessary
Plurality of solid radiation sources ('204 patent, claim 17)	Two or more separate radioactive solid sources placed in the inner spatial volume at the same time.	No construction necessary
Plurality of solid radiation sources ('142 patent, claim 6)	Not applicable.[2]	No construction necessary

Plaintiffs agree with SenoRx that "plurality of radioactive solid particles" and "plurality of solid radiation sources" should be construed the same way, Pl. Br. at 12, 13, 17, 25, and argue that "this term means what it says – 'a plurality of radioactive solid particles.'" *Id.* at 12. Plaintiffs assert, however, that "[t]here is no need to clarify that 'plurality' means 'two or more' or that the particles have to be 'separate.'" *Id.*

To the contrary, there is indeed a need to construe this term, because Plaintiffs do not mean what they say. Despite their "no construction necessary" position, Plaintiffs are not really saying that the term requires no further "clarification" in order to be properly understood. Rather, Plaintiffs hope to dissuade the Court from construing the term and then argue to the jury a meaning that is directly contrary to its plain meaning. "Clarification" that Plaintiffs' approach is incorrect is plainly required. Plaintiffs' true position is exposed on page 25 of their brief: "In fact, the plain meaning of this element encompasses a single radioactive seed inserted into different lumens at different times." *Id.* at 25 (emphasis added); *compare also id.* at 12 ("There

[1] The parties' constructions are summarized in the table attached herein at Appendix A.

[2] On May 30, 2008, Plaintiffs informed SenoRx that they are dropping their assertions of infringement of claim 6 of the '142 patent. Accordingly, SenoRx will not further address the limitations of claim 6.

is no need to clarify that . . . the particles have to be 'separate.'" (emphasis added)) *with id.* at 13 ("[T]here is no intrinsic basis for adding a restriction that multiple, separate, solid particles be placed in the inner spatial volume…" (emphasis in original)). Plaintiffs' infringement contentions likewise state the claim limitation of a "plurality" of sources is literally met by "a single solid radionuclide on a source wire . . . inserted sequentially into one or more predetermined locations." Ex. 11[3] (Pls' Infr. Cont. Appx. A) at 15 (emphasis added); *see also* Ex. 11 (Pls' Infr. Cont. Appx. B) at 16-17 ("one or more solid radiation sources") (emphasis added). Clearly, the parties have a real dispute about whether a claim limitation requiring a "plurality" of sources literally encompasses a "single" source – a dispute that is purely a matter of claim construction which is exclusively within the province of the Court to resolve. *See O2 Micro*, 521 F.3d at 1360 ("When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute.").

Substantively, SenoRx's proposed construction is plainly correct. "Plurality" means that there are two or more separate radioactive solid particles placed in the inner spatial volume at the same time. "Plurality" is a commonly-used claim term whose meaning is well-established. As the Federal Circuit has repeatedly observed, the term "'plurality,' when used in a claim, refers to two or more items, absent some indication to the contrary." *Dayco Prods., Inc. v. Total Containment, Inc.*, 258 F.3d 1317, 1327-28 (Fed. Cir. 2001) (emphasis added); *see also Bilstad v. Wakalopulos*, 386 F.3d 1116, 1122-23 (Fed. Cir. 2004) (affirming Board of Patent Appeals and Interferences' construction of "plurality" as a "numerical range . . . bounded by two . . . and . . . infinity"); *York Prods., Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1575 (Fed. Cir. 1996) ("The term means, simply, 'the state of being plural.'").

Furthermore, that the particles are "separate" " is supported by the claim term "plurality," which means "two or more," as well as by the specifications of the patents, which expressly distinguish a "single" radiation source from a "plurality" of separate radiation sources. *See* Ex. 1

[3] All exhibits ("Ex.") referenced herein are exhibits to the Declaration of Adam D. Harber in Support of SenoRx's Opening Claim Construction Brief, unless otherwise specified.

('813 patent), Figure 5; *id.* at col. 2:64-66; Ex. 2 ('204 patent), Figure 4; *id.* at col. 3:33-35, 5:1-4. For example, the '813 and '204 patents describe "individual radiation sources," which can not be understood in any way other than "separate." Ex. 1 ('813 patent), col. 3:7-8; Ex. 2 ('204 patent), col. 5:11.

Finally, the claim language also mandates that the particles are in the apparatus at the same time. The claims here are to specific devices and comprise a combination of elements. If every element of the claim is not present – *e.g.*, two or more radioactive particles at predetermined locations – then there is no claimed device. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005) ("To infringe an apparatus claim, the device must meet all of the structural limitations.") (emphases added). This is not a temporal limitation, but a structural limitation that requires every element of the claim – here, two or more radiation sources – to be present at the same time for an infringing apparatus to exist.

II. THE '813 AND '204 PATENTS.

A. "Predetermined Constant Spacing" ('813 Patent Claim 1).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
predetermined constant spacing between said inner spatial volume and the radiation transparent wall	Fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed inflatable chamber, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the outer chamber is the same (*i.e.*, the inner spatial volume and outer chamber are concentric and the same shape).	spacing predetermined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical

This claim limitation requires "a predetermined constant spacing" between the inner and outer spatial volumes. SenoRx's definition of "predetermined constant spacing" – a definition that is precise and explains the claim language and its consequence as set forth in the intrinsic evidence – should be adopted.

The '813 patent describes and claims as an essential feature of its invention the avoidance of "hot spots" in the tissue, *i.e.*, areas of tissue that receive a higher dose of radiation than other areas of tissue spaced equidistant from the radiation source. *See* SenoRx Opening Brief ("Op. Br.") at 5-6. The patent accomplishes this by ensuring that the inner volume (when it contains a radiation-emitting material) is centered in the outer volume and spaced apart from the outer surface of the device by a constant distance over their entire surfaces.[4] As Plaintiffs conceded in their opening brief: "The distance between the radiation source and the wall of the outer chamber can be made substantially constant. This embodiment permits the controlled delivery of radiation to a layer of tissue surrounding the surgical cavity." Pl. Br. at 4-5.

The plain claim language and the repeated description of the invention in the specification, *see* Op. Br. at 5-6, as well as applicants' distinction of prior art, *see* Op. Br. at 6, require "fixed" spacing. The patent is clear that by "constant," it means fixed, stating for example that "the distance from the spatial volume and the wall is maintained substantially constant over their entire surfaces," Ex. 1 ('813 patent), col. 1:55-57; that the "spacing between the wall of the inner chamber and the wall of the outer chamber remain generally constant," *id.* at 3:11-13, and that "In either the concentric spherical embodiment of FIG. 1 or the non-spherical configuration of FIG. 3, the spacing between the inner and outer chambers needs to be held somewhat constant to avoid 'hot spots.'" *Id.* at 4:13-16.

That the inner spatial volume and outer chamber are the same shape and concentric with each other follows as a consequence of the laws of geometry. If the inner spatial volume is spaced apart from the outer wall by a constant distance over their entire surfaces – the correct understanding of the claim – the two volumes necessarily are the same shape and concentric with each other (*i.e.*, sharing the same center and orientation). *See* Orton Decl. ¶ 25; [redacted]

[4] The '204 patent describes and claims the same features, as discussed below.

[5] Exs. 15-16 are exhibits to the Declaration of Adam D. Harber in Support of SenoRx's Responsive Claim Construction Brief.

Plaintiffs concede that "The '813 patent relates to an instrument comprising a concentric arrangement of an inner spatial volume and an outer spatial volume . . . ." Pl. Br. at 4. And, as they admitted at the *Markman* hearing in *Xoft*, a non-constant spacing results in the volumes not having the same shape: "if it's not constantly spaced, if it's, for example, an oblong figure in a spherical balloon, then you don't have a constant distance." Ex. 7 (*Xoft Markman* Tr.) at 71:3-5.[6]

Plaintiffs in their opening brief raise two issues with SenoRx's proposed construction. First, Plaintiffs state that their construction would allow "chang[ing] the spacing during treatment," Pl. Br. at 8, whereas SenoRx's would not. But there is no description whatsoever in any intrinsic evidence for Plaintiffs' contention that the invention allows the spacing to be changed during treatment, Pl. Br. at 8, and Plaintiffs do not provide any citation (even to their own expert) for any such understanding. *Id.*

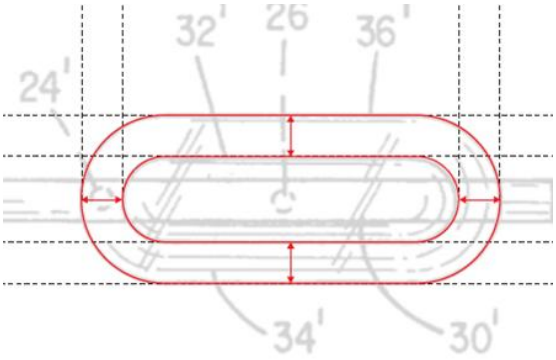
Plaintiffs' argument that "constant" spacing "may . . . change" is inherently self-contradictory and incorrect.

Plaintiffs also criticize SenoRx for construing the claim limitation the same for spherical balloons as for non-spherical balloons. That criticism is unfounded, and again, unsupported by the evidence. No intrinsic evidence suggests that "constant spacing" means something different for spherical balloon as compared to non-spherical balloons. To the contrary, the specification expressly states that the same configuration is needed to avoid hot spots: "In either the concentric spherical embodiment of FIG. 1 or the non-spherical configuration of FIG. 3, the spacing between the inner and outer chambers needs to be held somewhat constant to avoid 'hot spots.'" Ex. 3 ('813 patent), col. 4:13-16 (emphases added); *see also id.* at 3:11-13. Further,

[6] Furthermore, as discussed in SenoRx's opening brief at page 6, Plaintiffs distinguished the prior art Ishiwara patent from claim 1 because the "constant spacing" limitation required the same shape inner and outer surfaces, arguing that Ishiwara "teaches away from applicants' invention given the elongate, cylindrical shape of the radiation source employed and the oblong-shaped outer balloon surrounding it." Ex. 5 (Sep. 1, 1998 Am., '813 Prosecution History) at 6-7.

Plaintiffs are incorrect in asserting that SenoRx's construction would exclude Figure 3 (the non-spherical "hot dog in a hot dog"-shaped embodiment) from the scope of the claim.

Figure 3 of the patent has constant spacing over the entire surfaces of the two volumes, as seen from the annotated illustration below (annotations in red added):



And the patent expressly states that "the spacing between the wall of the inner chamber and the wall of the outer chamber remain[s] generally constant, such as is illustrated in FIG. 3." *Id.* at 3:11-13; *see also id.* at 4:13-16; Ex. 5 (Sep. 1, 1998 Am., '813 Prosecution History) at 6 ("In a second embodiment, attention is paid to the spacing between the inner and outer radiation transparent walls so that it is constant over the entire surfaces of the two chambers.") (emphasis added).

B. "Predetermined Spacing" ('204 Patent Claim 3).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
Predetermined spacing . . . between said inner spatial volume and the expandable surface element	Fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the wall of the expandable surface element, when inflated, which for each point on the wall or edge of the inner spatial	the distance between the inner spatial volume and the expandable surface element is determined in advance

	volume, the distance to the closest point on the expandable surface element is the same (*i.e.*, the inner spatial volume and expandable surface element are concentric and the same shape).	

Noting that "the '204 and '813 patents share similar disclosures," Plaintiffs largely repeat and incorporate their arguments relating to "predetermined constant spacing" in their discussion of "predetermined spacing." *See* Pl. Br. at 16. For the same reasons set forth above, those arguments should be rejected.

It is clear that in the '204 patent, as in the '813 patent, the spacing between the inner and outer volumes is fixed. The '204 patent (much like the '813 patent that it expressly incorporates) teaches that the claimed device should "ensur[e] that the spacing between the wall of the inner volume and the wall of the outer volume remain[s] generally constant," Ex. 2 ('204 patent), col. 5:22-27, which necessarily requires that the spacing be fixed. Plaintiffs should not be allowed to argue to the jury that "a predetermined spacing" may include circumstances where the spacing between the inner volume and outer volume changes during treatment (*i.e.*, once the expandable surface element has been inflated in a surgical cavity). There is no teaching whatsoever that the spacing between surfaces of the inner and outer volumes can change once the outer volume is inflated.

On this point, both parties' experts are in agreement. Dr. Verhey, Plaintiffs' expert, admits that the spacing of claim 3 is constant in his expert declaration on claim construction. *See* Ex. H to Altemus Decl. (Verhey Decl., (Oct. 12, 2006) Appx. C at 9-10).[7] He construes "predetermined spacing" to require that "spacing between the inner and outer spatial volumes can be set to a predetermined and constant value." *Id.* at 10:16-18, (emphasis added). For support, Dr. Verhey cites to the same portion of the specification as does SenoRx, *i.e.*, col. 5, ll. 22-32, that teaches:

[7] For clarity, Plaintiffs' exhibits are designated by lettering (A, B, C, etc.), whereas SenoRx's exhibits are designated by numbering.

> the spacing between the wall of the inner volume and the wall of the outer volume remain[s] generally constant. In either the concentric spherical embodiment of FIG. 1 or the non-spherical configuration of FIG. 5, this result can be achieved by careful placement of precision blown or molded polymer partitions or by using compressible foams or mechanical spacers in the form of webs joining the inner wall 32 to the outer wall 36.

Furthermore, in construing claim 4 of the '204 patent (the asserted claim here, which incorporates the "predetermined spacing" limitation of claim 3), Dr. Verhey again concludes the claim requires constant spacing: "the desired shape of the expandable surface element is that shape which provides the predetermined constant spacing between the inner spatial volume and the conformed surface of the resection cavity." Ex. H to Altemus Decl. (Verhey Decl., (Oct. 12, 2006) Appx. C at 9:22-24) (emphasis added); *see also* Orton Decl. ¶ 25.

C. Substantially Similar "Three-Dimensional Isodose Profile" ('204 Patent Claims 1, 17).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
three-dimensional isodose profile that is substantially similar in shape to the expandable surface element ('204 patent, claim 1); isodose profile having a shape substantially similar to the shape of the outer spatial volume ('204 patent, claim 17)	A final three-dimensional isodose profile that is substantially the same shape as the outer spatial volume expandable surface and is concentric with the outer spatial volume expandable surface.	No construction necessary.

For both claims 1 and 17, Plaintiffs contend that "the claim term means what it says" and "no further elaboration is necessary," because the "term has an ordinary and customary meaning to one of skill in the art." Pl. Br. at 17, 18. That is incorrect.[8] Plaintiffs again ask this Court to

[8] And, Plaintiffs are wrong that the ordinary meaning of "isodose profile" is used here. "Isodose profile," in its ordinary use, is a description of the dose received by points in tissue plotted as a function of distance, *e.g.*, a plot of dose versus distance from the center of a source, as shown at Fig. 4, curves 40 and 42. *See* Ex. H to Altemus Decl. (Verhey Decl., (Oct. 12, 2006) Appx. C at 8:15-17;

avoid construing a term in dispute so that they can have the freedom argue to the jury that it means something it plainly does not. *See O2 Micro*, 521 F.3d at 1360.

Without stating what they believe the meaning – ordinary or otherwise – of this term is, Plaintiffs dispute that the "three-dimensional isodose profile" recited by the claim means the cumulative absorbed dose of radiation administered by the apparatus to the tissue (in other words, the complete and final dose), and assert that no intrinsic evidence supports SenoRx's position. To the contrary, the patent's specification and prosecution history clearly indicate the "isodose profile" discussed in the claim is the representative curve showing the cumulative absorbed dose as delivered to the tissue by the device during treatment. Thus the patent's purpose is to provide an "absorbed dose within the target tissue" that is "substantially uniform in substantially every direction." Ex. 2 ('204 patent), col. 5:13-19. *See also id.* at col. 2:46-55 (The device must achieve a dose in the tissue "between a minimum prescribed absorbed dose for delivering therapeutic effects to tissue that may include cancer cells, and a maximum prescribed absorbed dose above which healthy tissue necrosis may result."); *id.* at col. 2:21-26 ("It is desirable to keep the radiation that is delivered to the tissue in the target treatment region within a narrow absorbed dose range . . . .") (emphases added). As explained in detail by Dr. Orton, Orton Decl. ¶ 50, the claim term is referring to the final, cumulative absorbed dose delivered by the device to the tissue, and the "isodose profile" of claim 1 should be construed accordingly.[9]

Plaintiffs also miss the mark in contending that SenoRx is "manufacturing" a requirement of concentricity. As discussed in SenoRx's opening brief at pages 7-8, the '204 patent's specification clearly describes the "substantially the same shape" limitation as requiring concentricity, and the applicants relied on concentricity in the prosecution history to distinguish the prior art. In particular, the applicants added the "substantially similar in shape" limitation to claim 1 to overcome the Williams '582 patent (among others). Ex. 9 (Dec. 20, 2000 Am., '204 Prosecution History) at 2, 10-16. Figure 7 of the Williams '582 patent (depicted at page 11 of

[9] Accordingly, should the Court so desire, the word "final" in SenoRx's proposed construction can augmented by "cumulative" or "absorbed".

SenoRx's opening brief) shows a device with an inner balloon and an outer balloon. Although the inner balloon is the same shape as the outer balloon, the applicants stated that Williams '582 did not meet the "substantially the same shape limitation." The reason was not based on shape, but because the inner balloon was not located concentric with the outer balloon: "As seen in Figure 7 of Williams, outer lumen 28B is not evenly spaced apart from inner lumen 28A that contains the radiation source. . . . [B]ecause the balloons are not equally spaced apart, Williams' apparatus cannot create an isodose profile that has substantially the same shape as the outer element." Ex. 9 (Dec. 20, 2000 Am., '204 Prosecution History) at 15-16 (emphases added). Prosecution disclaimer "promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003). Because the applicants clearly made the argument that "substantially the same shape" requires concentricity in order to gain allowance of claim 1, Orton Decl. ¶ 52, the public notice function demands the claim limitation be construed to include concentricity. *See, e.g., Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374-75 (Fed. Cir. 2008); *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005).

D. "Inner Spatial Volume" ('813 Patent Claim 1; '204 Patent Claim 1).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
inner spatial volume	A region of space surrounded by an outer spatial volume that is either enclosed by a distensible polymeric film wall or defined by the outside surface of a solid radionuclide sphere.	A region of space surrounded by an outer spatial volume that is either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide.

The term "inner spatial volume" is one unique to the '813 and '204 patents, and thus has no ordinary meaning to a person skilled in the art at the time of filing of the patent application. Accordingly, it is necessary to refer to the specification for the meaning: "Without a customary meaning of a term within the art, the specification usually supplies the best context for deciphering claim meaning." *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 991 (Fed. Cir. 2007). "[A]bsent such an accepted meaning, we construe a claim term only

as broadly as provided for by the patent itself." *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004) (emphasis added).

This is the approach the Court took in *Xoft*, and it is the approach SenoRx advocates here. As the Court discussed in *Xoft*, the inner spatial volume referred to in the patents is disclosed to be one of two structures, either a polymeric film-walled balloon or a solid radionuclide sphere, and that is the way the claims should be construed. Ex. 4 (*Xoft* Cl. Constr. Order) at 3-5, 16.

Plaintiffs dispute that the solid radionuclide must be spherical, contrary to this Court's prior construction. Pl. Br. at 5-7, 14. But a spherical source is precisely what the patent specification requires and is the only solid source disclosed. The portion of the specification Plaintiffs cite for their contention that the solid source can be non-spherical is directed to the polymeric film-walled balloons, hence the patent's discussion that "chambers 30 and 34" do not necessarily require spherical walls. Ex. 3 ('813 patent), col. 3:9-10. Likewise, dependent claim 13 of the '813 patent is limited to "spherical" inner and outer chambers (*e.g.*, balloons), and is not applicable to solid embodiments. Furthermore, it is undisputed that non-spherical sources were known at the time of the filing of the patent. Ex. H to Altemus Decl. (Verhey Decl. (May 21, 2008)) at 3-4. Despite that fact, the applicants made the conscious decision not to reference any of those sources, but instead to specifically state that "instead of having the inner spatial volume 30 defined by a generally spherical polymeric film wall as at 32, the catheter body member 12 may have a solid spherical radiation emitting material . . . ." Ex. 1 ('813 patent), col. 2:56-63 (emphasis added); *see also id.* at 2:64-65 ("inner spatial volume comprising a single solid sphere") (emphasis added); Ex. 2 ('204 patent), col. 4:44-50 (describing using "a solid spherical radiation emitting material 44 as the inner spatial volume 30. For example, radioactive micro spheres of the type available from the 3M Company of St. Paul, Minn., may be used.") (emphasis added).

Plaintiffs ask the Court to re-write the specification to capture non-spherical radionuclides such as SenoRx's cylindrical source. Pl. Br. 5-7, 14. The Court should not do so. Patentees justifiably are held to the descriptions of their inventions in their patents. Plaintiffs also suggest that the omission of non-spherical sources was a mere oversight. *Id.* at 6-7. The

prosecution history, however, reveals a different story. Indeed, the applicants distinguished prior art in part because of the prior art's use of cylindrical radionuclides: "In fact, it is proper to say that the Ishiwara et al. reference teaches away from applicants' invention given the elongate, cylindrical shape of the radiation source employed and the oblong-shaped outer balloon surrounding it." Ex. 5 (Sep. 1, 1998 Am., '813 Prosecution History) at 6-7 (emphasis added). The claim should be construed to cover what the applicants described – spherical solid radionuclides.

The polymeric film walled embodiment likewise should be construed "only as broadly as provided for by the patent itself," *Irdeto Access*, 383 F.3d at 1300, *i.e.*, to require that the wall be distensible. The patents consistently describe the polymeric film wall used to define the "inner spatial volume" to be distensible. *E.g.*, Ex. 2 ('204 patent), col. 2:56-60 ("the inner spatial volume can be defined by a distensible polymeric wall containing radioactive source material"); *id.* at col. 3:66-4:3 ("the distensible polymeric film walls may comprise a biocompatible, radiation resistant polymer"); *id.* at col. 5:22-23 ("inner and outer spatial volumes are created by inflatable membranes"); Ex. 1 ('813 patent), Abstract ("inner and outer distensible, spherical chambers"). Plaintiffs point to the Summary of Invention of the '813 patent to support their contention that the inner spatial volume need not be defined by a "distensible" film wall, stating that the specification "while referring to the 'polymeric film wall' does not describe it as 'distensible.'" Pl. Br. at 6. However, the portion of the specification quoted by Plaintiffs is plainly referring to the expandable surface of the outer spatial volume, about which there is no dispute that it is expandable. Thus, this actually supports SenoRx's contention – the patents, when discussing the "polymeric film walls" of the inflatable chambers, are referring to chambers whose walls are distensible.[10] Non-distensible polymeric walls are described nowhere in the patents, and were plainly not conceived of or claimed by the inventors as part of their invention.

[10] For this same reason, the amendment to claim 2 of the '204 patent, discussed by Plaintiffs at page 6 of their opening brief, is not relevant.

Accordingly, the "polymeric film wall" embodiment of the "inner spatial volume" should be construed to require "distensible" polymeric film walls.

E. "Means . . . For Rendering Uniform" ('813 Patent Claim 1).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
means . . . for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides	Function: Making the absorbed dose of radiation substantially more uniform between the surface of the outer chamber and a predetermined depth in the target tissue. Structure: A radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, a gas, barium sulfate, or their equivalents, that performs this function by absorbing or attenuating radiation.	Function: making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument Structure: a radiation absorbing or attenuating material, e.g. air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents

There are three fundamental disputes as to this claim term. First, the parties dispute the precise definition of the function in this means-plus-function claim element. Plaintiffs import a functional limitation – "to prevent overtreatment of body tissue at or close to the outer wall of the instrument" – that is not found in the claim language. This is erroneous, and should be rejected. *See Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1334 (Fed. Cir. 2006) ("A court errs when it improperly imports unclaimed functions into a means-plus-function claim limitation. . . . [T]his can occur during claim construction by defining a claimed function to require more than is actually claimed.").

Second, the parties dispute the extent to which the dose profile must be "rendered uniform." While the claim states, without qualification, "rendering uniform," in *Xoft*, this Court correctly rejected the argument that the profile must be completely uniform, *i.e.*, flat. *See* Ex. 4 (*Xoft* Cl. Constr. Order) at 8-10. However, SenoRx submits that construing the limitation as "substantially more uniform" is far closer to the claim language and the intent of the inventors (as shown in Figure 4) than simply "more uniform," which would encompass greater uniformity of any magnitude, however trivial. *See, e.g.*, Ex. 1 ('813 patent), claim 1 ("Apparatus for

delivering radioactive emissions to a body location with a uniform radiation profile . . . ."); *id.* at col. 1:36 ("as uniform as possible").

Finally, although the parties agree on the structure associated with the claimed function ("a radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, a gas, barium sulfate, or their equivalents"), they disagree about the way in which the structure performs this function. SenoRx contends that the "radiation absorbing or attenuating material" must perform the claimed function by absorbing or attenuating radiation.[11] Plaintiffs, on the other hand, contend the limitation is satisfied so long as a "radiation absorbing or attenuating" material is present, even if it does not render the dose uniform by absorbing or attenuating radiation. The patent clearly emphasizes on the nature of the structure as a radiation-absorbing material in performing the claimed function, and that accordingly should be reflected in the claim construction. Otherwise, it will be the case that any material that provides space between the inner and outer spatial volumes will fulfill the claim limitation – a plainly overbroad reading of the patent disclosure. As discussed in SenoRx's opening brief at pages 14-17, it is the radiation absorbing or attenuating material in the spatial volumes that was meant to affect the dose curve. *See also* Orton Decl. ¶¶ 37-38. The claim should be so construed.

F. "Inner Closed Chamber" ('813 Patent Claim 2).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
inner closed chamber	A compartment located completely inside of the outer chamber and closed off within the outer chamber.	No construction necessary.

As with previous terms, Plaintiffs again argue that the term "inner closed chamber" has a "plain meaning" and should not be construed. But, as before, the Court should construe this term as there is an actual dispute between the parties as to its meaning. The determination of precisely

[11] SenoRx has proposed adding this requirement to the structural limitation, although it could alternatively be added to the description of the function. Accordingly, should the Court not link the "by absorbing or attenuating radiation" limitation to the "structure," SenoRx respectfully requests the Court construe the function as "Making the absorbed dose of radiation substantially more uniform between the surface of the outer chamber and a predetermined depth in the target tissue by absorbing or attenuating radiation."

what "inner closed chamber" means cannot be and should not be left to the jury. Instead, the jury should be given clear guidance by this Court as to the scope of the claim limitation. *See O2 Micro*, 521 F.3d at 1360. SenoRx's proposed construction should be adopted because it precisely defines what the claim means, and is consistent with the intrinsic evidence and the inventor testimony.

Plaintiffs' sole argument is that SenoRx's construction cannot be correct because "it would exclude a preferred embodiment." But that confuses the role of independent and dependent claims. Dependent claims, such as the claim at issue here, are required to narrow the scope of the independent claims, which necessarily means that not all embodiments must be or should be covered by dependent claims. *See Glaxo Group Ltd. v. Ranbaxy Pharms., Inc.*, 262 F.3d 1333, 1336 (Fed. Cir. 2001) ("Dependent claims are generally narrower in scope than the claims from which they depend.").

[redacted] SenoRx's proposed construction is consistent with the clear import of the claim language as well as the rest of the evidence and should be adopted.

G. Providing a "Controlled Dose . . . to Reduce or Prevent Necrosis" ('204 Patent Claim 2).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
providing a controlled dose at	Controlling the ratio of the dose at the expandable surface of the outer spatial	controlling the ratio of the dose at the expandable surface of the outer

the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface	volume to the prescribed dose at the depth of interest in the target tissue so as to reduce or eliminate the risk of damage to healthy tissue in contact with the expandable surface as compared to devices in which the tissue is directly adjacent to the radiation source.	spatial volume to the prescribed dose at the depth of interest in the target tissue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface.

There are two primary differences in the parties' constructions of this term. First, SenoRx's construction tracks the language of the claim, and require the dose be controlled so as to "reduce or eliminate" necrosis, whereas Plaintiffs' construction does not incorporate the concept of "reducing" damage to the tissue. The inclusion of "reduce" in SenoRx's construction comes directly from the language of the claim and the specification of the patent. *See* Ex. 2 ('204 patent), col. 7:26-28 (the device allows physicians "to reduce or eliminate the risk of healthy tissue necrosis"). The patent also makes clear the answer to the question: "reduce" necrosis as compared to what? The specification addresses this in detail at Figures 7A-7D, as described in the specification at column 5:66-7:28. In particular, the devices of the invention are said to avoid "necrosis inducing radiation 'hot spots'" that were created by prior art devices "having a single spatial volume filled with a radioactive material," *id.* at col. 5:66-6:6, such that "the tissue [is] directly adjacent the wall" of the radiation-filled volume of the prior art device. *Id.* at 2:7-26. Thus, the applicants conclude, "[t]he capability of the apparatus of the invention to deliver absorbed doses deeper into the target tissue than prior interstitial brachytherapy devices while controlling the dose in proximity to the apparatus to reduce or eliminate the risk of healthy tissue necrosis allows for the use of brachytherapy in a greater number of cases." *Id.* at col. 7:23-28. In other words, the risk of necrosis is reduced by the claimed inventions by placing space in between the radiation source and the tissue, as compared to prior art devices in which the radiation source was placed directly adjacent the tissue.

Second, the parties disagree on how to characterize "necrosis." SenoRx's construction focuses on damage to "tissue," while Plaintiffs' construction focuses on cell death. As demonstrated by the patent, SenoRx clearly is correct that "necrosis" relates to systemic tissue damage, not merely cell death: "With increasing cell death comes increasing risk of necrosis or

tissue death in healthy tissue that is treated with a high dose of radiation." *Id.* at 6:55-57. Thus, cell death and necrosis, while related, are not the same thing, and the claim uses "necrosis." Plaintiffs assertion, that the claim requires not "lethally damag[ing] cells in healthy tissue in contact" with the balloon is found nowhere in the claims or specification and cannot be met by any device, as every internal radiation device that destroys cancer cells will lethally damage some cells in healthy tissue in contact with the device.

III. THE '142 PATENT

A. "Apparatus Volume" ('142 Patent Claims 1); "Located so as to be Spaced Apart from the Apparatus Volume" ('142 Patent Claim 1)

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
Apparatus volume (claim 1)	The three-dimensional region of space within the expandable outer surface.	Apparatus volume.
Three-dimensional apparatus volume configured to fill an interstitial void (claim 1)	The three-dimensional region of space within the expandable outer surface.	A three-dimensional geometric solid composed of an expandable outer surface.
Located so as to be spaced apart from the apparatus volume (claim 1)	Located outside (*i.e.*, not within) the apparatus volume.	Located so as to be not on or touching the apparatus volume.

In order to rewrite claim 1 of the '142 patent to preserve its validity – something that they are forbidden to do – Plaintiffs contort and twist the ordinary meaning of "volume." Plaintiffs' construction here not only is confused and confusing, but contradicts statements made in their brief and expert declaration. It also contradicts arguments made in the *Xoft* case (on which they prevailed), ignores the claim's definition of the "apparatus volume" and "expandable outer surface," and completely undermines the notice function of the claims of the patent. In amending claim 1 of the '142 patent during prosecution, Plaintiffs' representative wrote the claim to require an impossibility. Regardless of how Plaintiffs may feel about that now, the law is clear that the claims cannot be rewritten by this Court to say something different than what they say, nor can the same result be achieved under the rubric of claim construction. *Process Control Corp. v. HydReclaim Corp.* 190 F.3d 1350, 1357 (Fed. Cir. 1999) ("[W]e do not permit

courts to redraft claims."); *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("Courts do not rewrite claims; instead, we give effect to the terms chosen by the patentee.").

1. "Apparatus Volume."

Claim 1 requires in relevant part:

> an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;
>
> a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, . . .

Dr. Verhey, Plaintiffs' expert, describes his understanding of the first element of claim 1 as follows:

> [T]he "three-dimensional apparatus volume" is something that is defined by the "expandable outer surface." What this expandable outer surface defines is a <u>three-dimensional geometric solid (e.g., a sphere) having both volume</u> that fills an interstitial void created by the surgical extraction of diseased tissue <u>and a surface area</u> that defines an inner boundary of the target tissue being treated. Accordingly, in my opinion, the term "three-dimensional apparatus volume" means "a three-dimensional geometric solid composed of an expandable outer surface." By "solid," I mean a geometric shape, such as a sphere, having three dimensions and a surface area.

Ex. H to Altemus Decl. (Verhey Decl. (May 21, 2008)) at 5:4-10 (emphases added). Thus, Dr. Verhey understands the "three-dimensional apparatus volume" not to be a "region of space" defined the expandable surface – the plain and ordinary definition ascribed to "volume" by Plaintiffs in the *Xoft* case – but as encompassing "<u>both</u> volume . . . <u>and</u> a surface area." *Id.* (emphasis added). Expanding upon this view, Plaintiffs explain "by way of analogy, the skin of a basketball defines a three-dimensional basketball." Pl. Br. at 22, n.14.

The fatal flaw in Plaintiffs' construction is found in the first clause of the claim. That limitation clearly states and requires that the expandable outer surface and apparatus volume are different things, not that one is part of the other. Plaintiffs' construction would have the claim read as a nonsensical tautology: "An expandable outer surface defining a three-dimensional geometric solid composed of an expandable outer surface." Or, applying Plaintiffs' analogy, "the skin of a basketball defining a basketball composed of the skin of a basketball."

Dr. Verhey admits that if his definition of the claim term is applied "the patentee's use of the word 'volume' here is somewhat unusual." Ex. H to Altemus Decl. (Verhey Decl. (May 21, 2008)) at 5:11-12 (emphasis added). It certainly is. Indeed, more than "unusual," Dr. Verhey's definition of the "apparatus volume" as encompassing both the surface and the volume is contrary to '142 specification itself. "Three dimensional geometric solid" is a concept found nowhere in the intrinsic evidence. Instead, the specification states that the "present invention" of the '142 patent has "an expandable outer surface element defining an apparatus spatial volume." Ex. 3 ('142 patent), col. 2:55-64. This makes clear the inventors, in using the term apparatus volume, do so in exactly the way that SenoRx does – to delineate a volume that is a region of space, hence the description of the apparatus volume as a "spatial volume." *See also, e.g., id.* at 3:20-23 ("An interstitial brachytherapy apparatus of the invention may also be implemented in a device having an expandable outer surface defining an apparatus volume . . . ."). The specification never states or implies that the apparatus volume encompasses both the surface and the space inside of it, or that the expandable outer surface is part of the "apparatus volume."

Plaintiffs' construction and contentions also directly contradict their arguments in the *Xoft* litigation. Here, Plaintiffs contend their construction – that "apparatus volume" includes, and can refer to, the "outer expandable surface" of the device – is supported by the following passage from the '142 patent, which they cite and quote twice in their brief:

> By way of illustration, the specification describes an "outer spatial volume" that is "defined by an outer polymeric film barrier 32 that is appropriately spaced from the radioactive source." Col. 4:27-30.

Pl. Br. at 19, 22 (emphasis added). But, in the *Xoft* case, Plaintiffs argued directly to the contrary:

> Xoft's proposed construction of the term [outer spatial volume] . . . confuses the outer spatial volume with the "expandable surface element" that defines its boundary. The "outer spatial volume" is a region of space that is defined by an "expandable surface element" but it is not the "expandable surface element" itself. If the Court is inclined to construe "outer spatial volume," then the term should be construed as "a region of space defined by an expandable surface element and surrounding an inner spatial volume." This is consistent with the ordinary meaning of the claim term in view of the specification.

Ex. 6 (Cytyc Br.) at 19:21-28.[12] Plaintiffs were right before – the surface and the volume it defines are plainly different things.

Although Plaintiffs criticize SenoRx for reading the disputed terms of claim 1 out of context, it is Plaintiffs who have done so, leading to their flawed construction. Plaintiffs' argument simply assumes the conclusion Plaintiffs are trying to prove, all the while discounting the evidence to the contrary. SenoRx on the other hand starts, as is proper, with the language of the claim. *MSM Invs. Co., LLC v. Carolwood Corp.*, 259 F.3d 1335, 1338-39 (Fed. Cir. 2001). That language – which states that the "expandable outer surface defin[es] a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of tissue" – read in light of the specification and intrinsic evidence, compels the result that the apparatus volume is the region of space within the expandable outer surface. To decide to the contrary, as Plaintiffs urge the Court, requires impermissibly rewriting the claim language.

Finally, as noted in SenoRx's opening brief, the limitation of "an expandable outer surface defining an apparatus volume" is found not only in claim 1, but also in every other claim in the patent. Not one of those claims uses "apparatus volume" in the manner that Plaintiffs' contend. To the contrary, "apparatus volume" is used to refer to a volume, *i.e.*, a region of space defined by the expandable outer surface. *See, e.g.*, Claim 3 ("a catheter in communication with the apparatus volume"); Claim 4 (an "elongate member . . . taking on a substantially straight shape while being inserted through the catheter to the apparatus volume, and resuming an asymmetric shape when extended into the apparatus volume"); Claim 6 ("two elongate members extending into the apparatus volume"); *cf.* Claim 9 ("a radiation source disposed completely within and spaced apart from the expandable outer surface").

2. "Located so as to be Spaced Apart from the Apparatus Volume."

Contrary to what they say in their brief, Plaintiffs are not asking the Court to read the limitation of "a radiation source . . . located so as to be spaced apart from the apparatus volume"

[12] Notably, the '204 patent is expressly incorporated into the '142 patent. Ex. 3 ('142 patent, col. 1:6-12).

in the "context" of the specification. What Plaintiffs are really asking is for the Court to rewrite the claim, so that it reads "a radiation source . . . located so as to be spaced apart from the expandable outer surface." In so doing, Plaintiffs are championing a claim construction practice forbidden by the Federal Circuit. *See Process Control Corp.*, 190 F.3d at 1357; *K-2 Corp.*, 191 F.3d at 1364.

To be sure, Plaintiffs' newly-minted construction of this phrase – "located so as to be not on or touching the apparatus volume" – ignores the claim language. But it also is inconsistent with Plaintiffs' own construction of "apparatus volume." Plaintiffs' expert Dr. Verhey explains his construction of the "spaced apart" element as follows:

> As noted above, the three-dimensional apparatus volume is a geometric solid defined by the expandable outer surface that has both volume and surface area. Understood in this context, the phrase "located so as to be spaced apart from the apparatus volume" logically refers to the surface area of the apparatus volume that defines the inner boundary of the target tissue being treated. Accordingly, in my opinion, this claim phrase means "located so as to be not on or touching the apparatus volume."

Ex. H to Altemus Decl. (Verhey Decl. (May 21, 2008)) at 5:20-25. Dr. Verhey's constructions (adopted as Plaintiffs' constructions) are internally inconsistent in the following way: If the apparatus volume has "both volume and surface area," as Dr. Verhey opines, then the claim term "located so as to be spaced apart from the apparatus volume" must mean located so as to be spaced apart from "both volume and surface area." But that is not what Plaintiffs assert. Instead, Dr. Verhey cherry-picks a portion of the "apparatus volume" – the surface area (which Plaintiffs have strained to improperly insert into the meaning of "apparatus volume" in the first place) – and states that the radiation source has to be located not on or touching the surface, wholly ignoring the fact that their own definition of "apparatus volume" requires the radiation be spaced apart from the volume inside the surface as well. To further Plaintiffs' basketball analogy (where the "basketball" is the apparatus volume, *see* Pl. Br. at 22 n.14), "located so as to be spaced apart from the basketball" would mean that something inside of the basketball would be "spaced apart" from the basketball so long as it was not touching the basketball's surface. That plainly is an absurd construction, with no support in the intrinsic evidence whatsoever.

SenoRx's construction of the volume in accordance with its plain meaning as a "region of space" results in the conclusion that "spaced apart from the apparatus volume" means outside of the volume.

B. "Predetermined Asymmetric Isodose Curves" ('142 Patent Claims 1, 8).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
predetermined asymmetric isodose curves [with respect to the apparatus volume] ('142, claims 1, 8);	Isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume.	Predetermined isodose curves that are not symmetric with respect to the longitudinal axis of the apparatus volume.

Contrary to Plaintiffs' suggestion that "Hologic's construction comports with both the intrinsic and extrinsic record," Pl. Br. at 24, Plaintiffs' construction in fact reads into the claims a feature of the preferred embodiments, a practice that even they acknowledge is improper. Pl. Br. at 3 (quoting *JVW Enters., Inc. v. Interact Access., Inc.*, 424 F.3d 1324, 1335 (Fed. Cir. 2005) ("We do not import limitations into claims from examples or embodiments . . . ."). Rather than comporting with the claim language, the primary determinant in claim construction, Plaintiffs seek to add to the claims the limitation that the curves are asymmetric "with respect to the longitudinal axis of the apparatus volume." This limitation comes not from the claim, which plainly states that the asymmetry is "with respect to the apparatus volume," but from the description of some of the preferred embodiments. *See* Pl. Br. at 24 (referring to and quoting from the specification's description of "one example" of the invention, and the specification's description of the particular "configuration" of Figure 1).

As described in SenoRx's opening brief at pages 24-25, Plaintiffs' construction ignores the description in the patent of other configurations, where the asymmetric isodose curves are described more broadly than Plaintiffs' construction allows, or depicted in a way that contradicts their construction. *See, e.g.*, Ex. 3 ('142 patent), col. 2:56-3:11 ("In another example, the radiation source comprises a plurality of spaced apart solid radioactive particles disposed within the apparatus volume and arranged to provide a predetermined asymmetric isodose curve within

the target tissue.") (emphasis added); *see also, e.g.*, Ex. 14 (Verhey Depo. Tr.) at 146:13-17 ("Q. Is the radiation profile that is provided by the embodiment of Figure 3 asymmetric with respect to the longitudinal axis of the device? A. No, actually, it's not with respect to the longitudinal axis.").

Furthermore, Plaintiffs' assertion that SenoRx's construction is "unduly narrow" is also incorrect. In fact, SenoRx's construction is broader than Plaintiffs' construction. SenoRx's construction describes asymmetry in a way that captures every embodiment of the patent – isodose curves that are not concentric with the apparatus volume, isodose curves that do not share the same shape as the apparatus volume, or both. Contrary to Plaintiffs' suggestion, Pl. Br. at 24, SenoRx does not require that in every case the curves be shaped differently from the apparatus volume. Indeed, it is well understood that the curves could be shaped the same as the apparatus volume, but located so as to not be concentric with the apparatus volume (even on the longitudinal axis) in order to achieve an asymmetric dose curve.

C. "Asymmetrically Located and Arranged Within the Expandable Surface" ('142 Patent Claim 1).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
asymmetrically located and arranged within the expandable surface	Located and arranged inside the expandable surface so as not to be concentric with the expandable outer surface.	Located and arranged so as not to be on the longitudinal axis of the expandable surface.

For the same reasons advanced in connection with the "predetermined asymmetric isodose curves with respect to the apparatus volume," SenoRx's construction should be adopted, and Plaintiffs' attempt to read into the claim a limitation not found in the plain language ("on the longitudinal axis") should be rejected.

Furthermore, Plaintiffs misstate that SenoRx's construction excludes the preferred embodiments shown in Figures 3 and 4. Pl. Br. 23. The sources in those figures are not concentric (*i.e.*, sharing the same center and orientation) with the expandable outer surface,

because the sources are not arranged so as to have the same shape as the expandable outer surface. Orton Decl. ¶ 61. SenoRx's construction again is broader than Plaintiffs' construction, and covers all of the preferred embodiments.

D. "Being Provided on At Least Two Elongate Members" ('142 Patent Claim 6).

Claim Term	SenoRx's Proposed Construction	Plaintiffs' Proposed Construction
being provided on at least two elongate members extending into the apparatus volume	Not applicable.	No construction necessary

As discussed above at footnote 2, Plaintiffs today dropped their assertion of infringement of claim 6. Accordingly, SenoRx will not address this element.

CONCLUSION

For the foregoing reasons, the Court should adopt SenoRx's proposed constructions of the disputed terms of the '813, '204, and '142 patents.

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Respectfully submitted,

By: /s/ F.T.Alexandra Mahaney

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (admitted *pro hac vice*)
Aaron P. Maurer (admitted *pro hac vice*)
Rachel Shanahan Rodman (admitted *pro hac vice*)
Adam D. Harber (admitted *pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

APPENDIX A: SUMMARY OF THE PARTIES' PROPOSED CONSTRUCTIONS OF THE DISPUTED TERMS

'813 Patent

Claim Term	**SenoRx's Proposed Construction**	**Plaintiffs' Proposed Construction**
inner spatial volume (claim 1)	A region of space surrounded by an outer spatial volume that is either enclosed by a distensible polymeric film wall or defined by the outside surface of a solid radionuclide sphere.	A region of space surrounded by an outer spatial volume that is either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide.
predetermined constant spacing between said inner spatial volume and the radiation transparent wall (claim 1)	Fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed inflatable chamber, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the outer chamber is the same (*i.e.*, the inner spatial volume and outer chamber are concentric and the same shape).	spacing predetermined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical
means . . . for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides (claim 1)	Function: Making the absorbed dose of radiation substantially more uniform between the surface of the outer chamber and a predetermined depth in the target tissue. Structure: A radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, a gas, barium sulfate, or their equivalents, that performs this function by absorbing or attenuating radiation.	Function: making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument Structure: a radiation absorbing or attenuating material, e.g. air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents

inner closed chamber (claim 2)	A compartment located completely inside of the outer chamber and closed off within the outer chamber.	No construction necessary.
plurality of radioactive solid particles placed at predetermined locations (claim 12)	Two or more separate radioactive solid particles placed in the inner spatial volume at the same time at more than one predetermined location.	No construction necessary

'204 Patent

Claim Term	**SenoRx's Proposed Construction**	**Plaintiffs' Proposed Construction**
inner spatial volume (claim 1)	A region of space surrounded by an outer spatial volume that is either enclosed by a distensible polymeric film wall or defined by the outside surface of a solid radionuclide sphere.	A region of space surrounded by an outer spatial volume that is either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide.
three-dimensional isodose profile that is substantially similar in shape to the expandable surface element (claim 1)	A final three-dimensional isodose profile that is substantially the same shape as the outer spatial volume expandable surface and is concentric with the outer spatial volume expandable surface.	No construction necessary.
providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface (claim 2)	Controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target tissue so as to reduce or eliminate the risk of damage to healthy tissue in contact with the expandable surface as compared to devices in which the tissue is directly adjacent to the radiation source.	controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target tissue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface.
predetermined spacing . . . between said inner spatial volume and the expandable	Fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial	the distance between the inner spatial volume and the expandable surface element

surface element (claim 3)	volume and the wall of the expandable surface element, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the expandable surface element is the same (*i.e.*, the inner spatial volume and expandable surface element are concentric and the same shape).	is determined in advance
plurality of solid radiation sources (claim 17)	Two or more separate radioactive solid sources placed in the inner spatial volume at the same time.	No construction necessary
isodose profile having a shape substantially similar to the shape of the outer spatial volume (claim 17)	A final three-dimensional isodose profile that is substantially the same shape as the outer spatial volume expandable surface and is concentric with the outer spatial volume expandable surface.	No construction necessary.

'142 Patent

Claim Term	**SenoRx's Proposed Construction**	**Plaintiffs' Proposed Construction**
apparatus volume (claim 1)	The three-dimensional region of space within the expandable outer surface.	Apparatus volume.
three-dimensional apparatus volume configured to fill an interstitial void (claim 1)	The three-dimensional region of space within the expandable outer surface.	A three-dimensional geometric solid composed of an expandable outer surface.
located so as to be spaced apart from the apparatus volume (claim 1)	Located outside (*i.e.*, not within) the apparatus volume.	Located so as to be not on or touching the apparatus volume.

asymmetrically located and arranged within the expandable surface (claim 1)	Located and arranged inside the expandable surface so as not to be concentric with the expandable outer surface.	Located and arranged so as not to be on the longitudinal axis of the expandable surface.
predetermined asymmetric isodose curves [with respect to the apparatus volume] (claim 1)	Isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume.	Predetermined isodose curves that are not symmetric with respect to the longitudinal axis of the apparatus volume.
plurality of solid radiation sources (claim 6)	Not applicable. See footnote 2, *supra*.	No construction necessary
predetermined asymmetric isodose curves [within the target tissue] (claim 6)	Not applicable. See footnote 2, *supra*.	Predetermined isodose curves that are not symmetric with respect to the longitudinal axis of the apparatus volume.
being provided on at least two elongate members extending into the apparatus volume (claim 6)	Not applicable. See footnote 2, *supra*.	No construction necessary
apparatus volume (claim 6)	Not applicable. See footnote 2, *supra*.	Apparatus volume.
predetermined asymmetric isodose curves [with respect to the apparatus volume] (claim 8)	Isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume.	Predetermined isodose curves that are not symmetric with respect to the longitudinal axis of the apparatus volume.

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On May 30, 2008, I served a copy(ies) of the following document(s):

DEFENDANT SENORX, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF [REDACTED VERSION]

on the parties to this action by the following means:

Henry C. Su (suh@howrey.com) Katharine L. Altemus (altemusk@howrey.com) HOWREY LLP 1950 University Avenue, 4th Floor East Palo Alto, CA 94303 Telephone: (650) 798-3500 Facsimile: (650) 798-3600	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP
Matthew Wolf (wolfm@howrey.com) Marc Cohn (cohnm@howrey.com) HOWREY LLP 1229 Pennsylvania Avenue, NW Washington, DC 20004 Telephone: (202) 783-0800 Facsimile: (202) 383-6610	Attorneys for Plaintiffs HOLOGIC, INC. CYTYC CORPORATION and HOLOGIC LP

☒ (BY MAIL) I placed the sealed envelope(s) for collection and mailing by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily familiar with WSGR's practice for collecting and processing of correspondence for mailing with the United States Postal Service, said practice being that, in the ordinary course of business, correspondence with postage fully prepaid is deposited with the United States Postal Service the same day as it is placed for collection.

☒ (BY ELECTRONIC MAIL) I caused such document(s) to be sent via electronic mail (email) to the above listed names and email addresses.

☐ (BY PERSONAL SERVICE) I caused to be delivered by hand to the addressee(s) noted above. I delivered to an authorized courier or driver to be delivered on the same date. A proof of service signed by the authorized courier will be filed with the court upon request.

☐ (BY OVERNIGHT DELIVERY) I placed the sealed envelope(s) or package(s), to the addressee(s) noted above, designated by the express service carrier for collection and overnight delivery by following the ordinary business practices of Wilson Sonsini Goodrich & Rosati, 12235 El Camino Real, Ste. 200, San Diego, CA. I am readily familiar with WSGR's practice for collecting and processing of correspondence for

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☐ (BY FACSIMILE) I caused to be transmitted by facsimile machine (number of sending facsimile machine is (858) 350-2399 at the time stated on the attached transmission report(s) by sending the documents(s) to (see above). The facsimile transmission(s) was/were reported as complete and without error.

☒ (BY CM/ECF) I caused such document(s) to be sent via electronic mail through the Case Management/Electronic Case File system with the U.S. District Court for the Northern District of California.

I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on May 30, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

Bruce R. Genderson (*admitted pro hac vice*)
Aaron P. Maurer (*admitted pro hac vice*)
Rachel Shanahan Rodman (*admitted pro hac vice*)
Adam D. Harber (*admitted pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029

Attorneys for Defendant and Counterclaimant
SENORX, INC.

IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P., Plaintiffs, v. SENORX, INC., Defendant.	CASE NO.: 08-CV-0133 RMW **DECLARATION OF ADAM D. HARBER IN SUPPORT OF DEFENDANT SENORX, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF**
SENORX, INC., Counterclaimant, v. HOLOGIC, INC., CYTYC CORP., and HOLOGIC L.P., Counterdefendants.	Date: June 25, 2008 Time: 2:00 p.m. Courtroom: 6, 4th Floor Judge: Hon. Ronald M. Whyte

I, Adam D. Harber, declare that I am an associate at the law firm of Williams & Connolly LLP, admitted pro hac vice to practice before this Court in the above-captioned matter. I serve as outside counsel for Defendant SenoRx, Inc. ("SenoRx"). The following declaration is based on my personal knowledge, and if called upon to testify, I could and would competently testify as to the matters set forth herein.

1. Attached hereto as Exhibit 15[1] is a true and correct copy of excerpts of the transcript of the Deposition of Jeffrey F. Williamson (May 19, 2008).

2. Attached hereto as Exhibit 16 is a true and correct copy of excerpts of the transcript of the Deposition of James F. Dempsey (May 24, 2008).

3. Attached hereto as Exhibit 17 is a true and correct copy of excerpts of the transcript of the Deposition of Timothy J. Patrick (May 29, 2008).

[1] The numbers assigned to exhibits attached to this Declaration run consecutively from the exhibit numbers of those attached to the Declaration of Adam D. Harber in Support of Defendant SenoRx, Inc.'s Opening Claim Construction Brief.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 30, 2008

By: _____
Adam D. Harber

CERTIFICATE OF SERVICE
U.S. District Court, Northern District of California,
Hologic, Inc. et al. v. SenoRx, Inc.
Case No. C-08-0133 RMW (RS)

I, Kirsten Blue, declare:

I am and was at the time of the service mentioned in this declaration, employed in the County of San Diego, California. I am over the age of 18 years and not a party to the within action. My business address is 12235 El Camino Real, Ste. 200, San Diego, CA, 92130.

On May 30, 2008, I served a copy(ies) of the following document(s):

DECLARATION OF ADAM D. HARBER IN SUPPORT OF DEFENDANT SENORX, INC.'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

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I declare under penalty of perjury under the laws of the United States that the above is true and correct, and that this declaration was executed on May 30, 2008.

Kirsten Blue

F.T. Alexandra Mahaney, State Bar No. 125984
Natalie J. Morgan, State Bar No. 211143
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
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Attorneys for Defendant and Counterclaimant
SENORX, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

SENORX, INC.,

Counterclaimant,

v.

HOLOGIC, INC., CYTYC CORPORATION and HOLOGIC L.P.,

Counterdefendants.

Case No. C-08-0133 RMW (RS)

DEFENDANT AND COUNTERCLAIMANT SENORX, INC.'S NOTICE OF MANUAL FILING

Date: June 25, 2008
Time: 2:00 p.m.
Ct. Rm: Courtroom 6, Fourth Floor
Judge: Hon. Ronald M. Whyte

Regarding: **Exhibits 15, 16 and 17 to the Declaration of Adam D. Harber in Support of Defendant SenoRx, Inc.'s Responsive Claim Construction Brief and confidential version of Defendant SenoRx, Inc's Responsive Claim Construction Brief.**

This filing is in paper or physical form only, and is being maintained in the case file in the Clerk's office. If you are a participant in this case, this filing will be served in hard-copy shortly. For information on retrieving this filing directly from the court, please see the court's main web site at http://www.cand.uscourts.gov under Frequently Asked Questions (FAQ).

This filing was not efiled for the following reason(s):

[X] Item(s) Under Seal

Dated: May 30, 2008

Respectfully submitted,

By: s/F.T. Alexandra Mahaney

F.T. Alexandra Mahaney, State Bar No. 125984
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
12235 El Camino Real, Suite 200
San Diego, CA 92130
Telephone: (858) 350-2300
Facsimile: (858) 350-2399
Email: amahaney@wsgr.com

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SENORX, INC.

CERTIFICATE OF SERVICE
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on the parties to this action by placing them in a sealed envelope(s) addressed as follows:

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Kirsten Blue